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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,112	01/14/2002	William H Cork	F-5629 (CORK 100 US)	2485

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EXAMINER

CECIL, TERRY K

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/031,112

Applicant(s)

CORK ET AL.

Examiner

Mr. Terry K. Cecil

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 34-45, 54-64 and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by Mian et al. (U.S. 2001/0055812 A1), hereinafter “Mian”. As shown in e.g. figure 19, Mian discloses a centrifugal blood processing system having a location (C1) where the patient places his lanced finger (see left-side-middle of figure 17F and [0216]); at this time, the flow path of C1 is in communication with the vascular system of the patient. A plurality of flow paths C2-C5 are provided for receiving the separated components (0280) to (0285), wherein the components can be withdrawn from the device (0286). The device is a microanalytic system that includes electromechanical means (0099) and microchannels that include microsensors as disclosed by the applicant (0177) to (0208) and (0218) [as in claim 34]. One parameter measured is “count” (figure 17O) and hematocrit [0280]. The information is used by the controller to optimize the separation for controlling the rotation of the disk [see 0283 and 0172] [as in claim 35]. Since the first flow path for inputting the blood sample communicates with the patient and the second and third flow paths communicate with the first flow path, the third flow path also communicates

Art Unit: 1723

with the patient [as in claim 36]. The device determines the hematocrit value and the microchannel is treated with heparin to prevent clotting (0280) [as in claim 36]. As explained above, sensors are included in the flow channels to determine the flow rates therethrough (0204), the ratio of the flows (quantity) through respective channels is controlled by controlling rotational speed to optimize the separation of the blood into its components (quality) [as in claims 38-39]. The cells in the channel can also be quantified (0287). As for claims 40-45 the flow in each channel is controlled and divides the sample into its components, i.e. RBC, WBC, platelets, wherein each component can be considered as “desired” or “undesired” depending upon which component is desired to be measured. As for claim 37, that the controller controls the treatment device in response to the signal to avoid one or more deleterious consequences to the human subject, such is geared more to the intended use of the apparatus and as claimed can be interpreted broadly. For example, the when controller controls the operation of the disk in order to optimize the separation of the blood components such could be used to for proper diagnosing a disease of the patient, such that the deleterious consequences of mis-diagnosis is avoided. As for claims 54-64 and 73, Mian teaches each flow path to contain sensors (see the information as the bottom of figure 17G) and respective sensors for counting the cells withdrawn from each flow path [0286]. The aforementioned rejection and comments of intended use of claims 34-45 apply *mutatis mutandis* to claims 54-64 and 73. As for claims 46-49, 50-51, 53, 65-67, 69-70, 72, 74-76, 78-79 and 81. Mian teaches circuitry for storing information and including a read-only (nonvolatile memory) that relates to the sensed data for the patient [see 0224, 0225, 0227, 0104].

Art Unit: 1723

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kowarski (U.S. 4,006,743) in view of Yager et al. (U.S. 5,932,100). Kowarski teaches a system for continuously withdrawing blood from a patient, treating the withdrawn sample by microdiffusion device 64, and sensing system 76 to analyze the components of the blood. Kowarski does teach a mems system. However, such is taught in Yager. Yager teaches a MEMS sensing device for continuous flow from a patient that treats the withdrawn sample by extraction to produce two flows that are analyzed by MEMs sensors (col. 12, lines 4-25). It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the blood processing system of Yager in the invention Kowarski, since Yager teaches the benefits of production economy, small in size, and a continuous processing mode (col. 3, lines 18-25).

Art Unit: 1723

5. Claims 24-45, 47, 54-64, 66, 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langley et al. (U.S. 5,496,265) in view of Altendorf et al. (U.S. 5,726,751).

The aforementioned statements concerning intended use apply mutatis mutandis to the following rejection. Langley teaches a system for separating the components of blood continuously withdrawn from a donor (figure 2) with a centrifuge 18 into separate container. A controller is used to optimize the separation depending upon the desired type and amount of component to be collected. Langley collects data concerning the separation including cell counter using a cell counter (lines 16-44) but does teach a mems device. However, such is taught by Altendorf. Altendorf teaches a mems-type sensor including a silicon wafer for determining the characteristics of a flow, including cell count. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the mems-type cytometer of Altendorf in each separation line of Langley, since Altendorf teaches the benefit of simple fabrication, disposability, and is sensitive and versatile (cols. 1 and 2).

6. Claims 47-53, 66-72, 75-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langley in view of Altendorf, and in further view of Leuenberger. As explained above, Langley, in view of Altendorf teaches a data storage system. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to for the system to include non-volatile memory so the information recorded cannot be changed. Luenberger teaches a bar code label containing information about the contents of a collection bag. Note that a bar code is a type of icon. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the bar code of Leuenberger on each of the

Art Unit: 1723

collections containers of Langley, as modified by Altendorf, since Leuenberger teaches the benefit of efficiently retrieving information about the bag at a blood bank.

7. Claims 46, 55 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langley in view of Altendorf, and in further view of Antwiler (U.S. 5,437,598). Antwiler teaches a flow control module (14) for controlling flow to a centrifuge. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the manifold module 14 of Antwiler in the invention Langley, as modified by Altendorf, since Antwiler teaches the benefit of controlling flow to a centrifuge for collecting blood components.

#### ***Response to Arguments***

8. Applicant's arguments filed 6-22-2004 have been fully considered but they are not persuasive because of the following reasons:

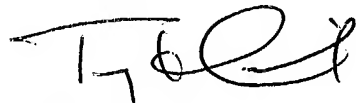
- In order to distinguish from Mian, applicant has added that the sensor is for sensing either a biological or a chemical characteristic of the fluid. This phrase limits the intended use of the sensor. As shown in the paragraphs of Mian indicated above, the controller uses this information to determine cell count and hematocrit and also uses the recorded data to optimize the rotation of the disk. As for the phrase "wherein said first fluid flow path is in continuing direct communication" with a vascular system of the human subject, this limitation is geared more to the way in which the apparatus is used. In Mian, blood from the lanced fingered is drawn into the first flow path by capillary action. As long as the finger is in the lancing position the "continuous" direct contact is effected. Did applicant intend to

Art Unit: 1723

claim the structure of venous and arterial sets (including tubing and needles) which would allow blood to continuously flow to the system and back to the patient as in his specification? Such structure has not been claimed and is not part of the elected invention. Such structure is also known in the art, e.g. prince. It is also pointed out that the added limitation of “continuing and direct communication” does not require the flow path of the system to be in contact with the human vascular system for any definite amount of time—as admitted by the applicant (page 6 of 8, lines 6-8). The added limitation fails to further structurally define the claimed apparatus.

## 9. Contact Information:

- Examiner Mr. Terry K. Cecil can be reached at (571) 272-1138 at the Carlisle campus in Alexandria, Virginia for any inquiries concerning this communication or earlier communications from the examiner. Note that the examiner is on the increased flextime schedule but can normally be found in the office during the hours of 8:30a to 4:30p, on at least four days during the week M-F.
- Wanda Walker, the examiner's supervisor, can be reached at (571) 272-1151 if attempts to reach the examiner are unsuccessful.
- The Fax number for this art unit for official faxes is 703-872-9306.
- Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mr. Terry K. Cecil  
Primary Examiner  
Art Unit 1723

TKC  
September 17, 2004